Supreme Court, U.S.
FILED

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No.

IN THE SUPREME COURT
OF THE UNITED STATES

OCTOBER TERM, 1996

JOHN D. COPANOS,

Petitioner,

v.

FOOD AND DRUG ADMINISTRATION
and
UNITED STATES,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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39 pp

QUESTION PRESENTED

Did the court of appeals abuse its discretion, and violate the constitutional due process limits on the common-law exhaustion of remedies doctrine, by refusing to consider the merits of petitioner's legal arguments for review of an agency order permanently debarring him from employment in the drug industry, where petitioner's basis for substantive judicial review was exceptionally strong and the governmental interest favoring exhaustion was virtually nonexistent?

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OPINIONS BELOW

The judgment of the court of appeals was not published in any official or unofficial reporter but is set forth in the Appendix at A-1. The final order of permanent debarment issued by the Food and Drug Administration ("FDA") is reported at 61 Fed. Reg. 9711 (March 11, 1996), and is set forth in the Appendix at A-3.

JURISDICTION

The judgment of the court of appeals was entered on January 29, 1997. A timely Petition for Rehearing was denied on March 28, 1997, and the court's order is attached in the Appendix at A-12. This petition is filed within ninety days of the denial of the Petition for Rehearing and is timely under Rule 13 of the Rules of the Supreme Court of the United States. This court has jurisdiction to review the decision of the court of appeals under 28 U.S.C. §1254(1).

CONSTITUTIONAL PROVISIONS, STATUTES AND REGULATIONS

The full text of the Constitutional provisions, statutes and regulations involved in this petition and cited below are provided in Appendix B:

U.S. Const. amend. V
21 U.S.C. §335a(a)(2)
21 U.S.C. §335a(j)(1)
21 U.S.C. §12.24
21 U.S.C. §12.30

STATEMENT OF THE CASE

On November 13, 1989, Petitioner John D. Copanos entered a plea of guilty to two felony counts of adulteration and misbranding of drug products in violation of provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §321 et seq. (1994). At the time of the events underlying his conviction, as well as at the time of his conviction and sentencing, FDA possessed no statutory authority to impose debarment of any kind for any reason. FDA was not granted such authority until passage of the Generic Drug Enforcement Act of 1992 ("GDEA"), Pub. L. No. 102-282, 106 Stat. 149 (1992), more than two years after Mr. Copanos' conviction and more than six years after the underlying events on which it was based. At the time Mr. Copanos entered his guilty plea in 1989, there was no basis upon which it could be contemplated that the FDA might take administrative action, based upon a statute enacted more than two years after his conviction, to debar him for life from working in the pharmaceutical industry.

The GDEA, as enacted, does not include any express language authorizing the retroactive application of the mandatory debarment provision underlying this case -- 21 U.S.C. §335a(a)(2). The legislative history is similarly devoid of evidence of clear congressional intent favoring the retroactive application of §335a(a)(2) and, if anything, supports the opposite conclusion, i.e., that Congress intended §335a(a)(2) to apply only to acts committed subsequent to its enactment or, at the very least, left its retroactive application unresolved. Clear and explicit retroactivity language was contained in several predecessor bills.[1] That language was intentionally omitted

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1

For example, H.R. 4810, a predecessor of the GDEA introduced in the House of Representatives on May 15, 1990, contained a provision explicitly stating that its

from the GDEA following sustained criticism on fairness and constitutionality grounds. One of the strongest critics of the retroactivity language in the predecessor bills was the chairman of the House subcommittee primarily responsible for the debarment legislation, Congressman Henry A. Waxman, who observed that "many of those who have reviewed the bill believe that the penalties are too harsh [and] are unfairly retroactive." Penalties for Illegal Activities in the Approval of Drugs: Hearing on H.R. 4810 Before the Subcomm. On Health and the Environ. Of the House Comm. On Energy and Commerce, 101st Cong., 2d Sess. 2 (1990).

Notwithstanding the statutory text and the legislative history negating retroactive application of §335a(a)(2), FDA initiated debarment proceedings against Mr. Copanos on November 9, 1994, based upon his pre-enactment conviction almost five years earlier. In its debarment notice, FDA explicitly informed Mr. Copanos that his sole administrative right to contest debarment was an opportunity to request a hearing and, further, that his submission to the agency "must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing." 59 Fed. Reg. 55846 (Nov. 9, 1994) (emphasis added). FDA's procedural regulations governing debarment went even further, notifying Mr. Copanos that "[a] hearing will not be granted on issues of policy or law." 21 C.F.R. §12.24(b)(1) (1996).

In accordance with FDA's notice and procedural regulations, Mr. Copanos submitted a request for hearing that

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mandatory debarment provision "shall apply to acts which occurred after September 1, 1984." H.R. 4810, 101st Cong., 2d Sess. §2 (1990). Likewise, S. 2683, a similar, though broader, debarment bill introduced in the Senate on May 24, 1990, included an express retroactivity provision stating: "The provisions of this section [i.e., debarment] shall apply to acts or omissions which occurred prior to enactment of this section." S. 2683, 101st Cong., 2d Sess., §2 (1990).

was overwhelmingly fact-based, seeking to raise a genuine and substantial issue of fact requiring a hearing.[2] On March 11, 1996, FDA denied Mr. Copanos' request for hearing and issued a final order of permanent debarment. As a result of that order, Mr. Copanos was and is categorically prohibited for the rest of his life from being employed by or providing services in any capacity to a person with an approved or pending drug product application.

On April 22, 1996, Mr. Copanos filed a timely Petition for Review in the United States Court of Appeals for the District of Columbia Circuit pursuant to 21 U.S.C. §335a(j)(1) in which he raised two purely legal objections to FDA's final order: (1) that FDA could not, consistent with this Court's decision in Landgraf v. USI Film Products, 511 U.S. 244 (1994), retroactively apply to him the debarment provision of the GDEA because his conviction predated enactment of the statute; and (2) that FDA had acted in an arbitrary and capricious manner and in violation of his constitutional right to equal protection of the law by applying the debarment statute retroactively against him but not against others in an identical legal status.

The court of appeals denied Mr. Copanos' petition for review on January 29, 1997, holding that he had waived these legal arguments by failing to present them first to FDA. Although the court of appeals acknowledged that FDA's notice and regulations indicate that hearings are granted only where genuine issues of fact exist, it nevertheless concluded that

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2 In his request for a hearing, Mr. Copanos raised at least nine discrete factual objections to his proposed debarment and only one argument which might be characterized as purely legal or policy-based. He did not explicitly raise the statutory retroactivity issue.

application of the waiver doctrine was appropriate because, in its view, Mr. Copanos "could have" raised legal arguments in his request for a hearing or in a petition for rehearing. Moreover, the court of appeals held that FDA's predetermination of the retroactivity issue in four prior published orders was "irrelevant" to the waiver issue, since Mr. Copanos had not himself raised the retroactivity issue before the agency. On March 28, 1997, the court of appeals denied a timely Petition for Rehearing and Suggestion for Rehearing *In Banc*.

ARGUMENT

Certiorari should be granted in this case because:

1. The court of appeals has departed from the accepted and usual course of judicial proceedings and abused its discretion in applying the common-law exhaustion of remedies doctrine so as to infringe Mr. Copanos' constitutional due process rights, thereby calling for an exercise of this court's supervisory powers. See Supreme Court Rule 10(a); and

2. The court of appeals has decided an important federal question regarding exhaustion of administrative remedies in a way that conflicts with relevant decisions of this Court, particularly McCarthy v. Madigan, 503 U.S. 140 (1992). See Supreme Court Rule 10(c).

A. The Court Of Appeals' Rigid Application Of The Waiver Doctrine In This Case Is Fundamentally Unfair And Cannot Be Reconciled With The Fifth Amendment Due Process Clause

It is well-established that the common-law exhaustion of remedies doctrine, of which the waiver doctrine is but a part, must be applied flexibly, practically and with an eye toward its underlying purposes. McCarthy, 503 U.S. at 146; McKart v. United States, 395 U.S. 185 (1969); Cutler v. Hayes, 818 F.2d 879, 890 (D.C. Cir. 1987). The reason for this mandatory flexibility is that "federal courts are vested with a virtually unflagging obligation to exercise the jurisdiction given them." McCarthy, 503 U.S. at 146. Indeed, the failure of a federal court to exercise jurisdiction when appropriate can constitute an independent violation of the fundamental right to due process of law guaranteed by the Fifth Amendment to the United States Constitution. Cf. Richards v. Jefferson County, Alabama, 116 S.Ct. 1761, 1765 (U.S. 1996).

In this case, the court of appeals has failed to heed the admonitions of this Court to apply the exhaustion doctrine flexibly and pragmatically so as to avoid serious constitutional questions. As demonstrated in section B below, virtually none of the purposes underlying the exhaustion doctrine are served by denying Mr. Copanos a substantive hearing pursuant to 21 U.S.C. §335a(j)(1) on his legal objections in the court of appeals.

Although the court of appeals undoubtedly has broad discretion in applying the waiver doctrine, that discretion is not unfettered. It is well-established that "[t]he opportunity to be heard is an essential requisite of due process of law in judicial proceedings." Richards, 116 S.Ct. at 1765 n. 4. For this

reason, this Court has recognized that "there are constitutional limitations upon the power of courts, even in aid of their own valid processes, to dismiss an action without affording a party the opportunity for a hearing on the merits of his cause." Societe Internationale v. Rogers, 357 U.S. 197, 209 (1958).

Although Petitioner is not aware of any prior case applying this due process guarantee to a federal court's application of the waiver doctrine, this Court recently addressed a similar issue involving an overly restrictive application of the doctrine of *res judicata* by a state Supreme Court. In Richards, this Court unanimously held that petitioners were deprived of the due process of law guaranteed by the Fourteenth Amendment when the Alabama Supreme Court refused to hear their case on the merits, holding that they were bound under *res judicata* principles by a prior adjudication to which they were not parties. 116 S.Ct. at 1765.

The reasoning applied by the Court in Richards is equally applicable to the present case. Like the "extreme" application of the *res judicata* doctrine at issue in Richards, the court of appeals' application of the waiver doctrine in this case is unduly rigid because, as expanded upon below, (a) FDA's notice and regulations explicitly indicated that FDA would not consider legal or policy arguments and that Mr. Copanos instead should limit his response to purely factual issues; (b) FDA already had predetermined the retroactivity issue in four prior published decisions; and (c) the institutional interests favoring exhaustion in this matter are particularly attenuated.

Consequently, the court of appeals' refusal to consider Mr. Copanos' substantive legal arguments, like the Alabama Supreme Court's refusal to entertain the substantive legal arguments of the petitioners in Richards, threatens to deprive Mr. Copanos of his fundamental right to a full and fair hearing

by the court of appeals guaranteed by Section 306(j)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §335a(j)(1), and by the Fifth Amendment to the United States Constitution.

B. Virtually None Of The Purposes Underlying The Exhaustion Doctrine Are Served By The Court Of Appeals' Denial Of Mr. Copanos' Petition

The court of appeals' decision constitutes an "extreme" application of the exhaustion doctrine — and an abuse of discretion — because virtually none of the purposes underlying the exhaustion doctrine are served by the court's refusal to consider the merits of Mr. Copanos' legal arguments.

The requirement imposed by the court of appeals that Mr. Copanos first raise his legal objections with FDA as a precondition to presenting those issues to a reviewing court is not a prerequisite imposed by statute or regulation. It is instead grounded solely on the court's inherent powers under the common-law doctrine of exhaustion of remedies. See McCarthy, 503 U.S. at 144. Consequently, the court of appeals should have employed the "intensely practical" balancing test prescribed by this Court in McCarthy, which is intended to weigh the litigant's interest in obtaining prompt judicial review against the government's interests in requiring exhaustion. Id. at 146. Because the balance of equities under this test weighs heavily in favor of judicial review of Mr. Copanos' legal claims, the court of appeals abused its discretion, and violated Mr. Copanos' Fifth Amendment due process rights, by refusing to review those claims on the merits.

1. FDA's Notice And Procedural Regulations Created "Some Doubt" As To Whether FDA Would Consider Purely Legal Arguments

Under the balancing test prescribed in McCarthy, Mr. Copanos' interest in obtaining judicial review of his legal objections is particularly compelling because FDA's notice and regulations pertaining to debarment orders created serious doubts as to whether FDA was empowered or willing to address and dispose of purely legal issues. See id. at 146. In its debarment notice, FDA explicitly informed Mr. Copanos that his submission to the Agency "must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing." 59 Fed. Reg. 55846 (emphasis added). FDA's procedural regulations governing debarment further informed Mr. Copanos that "[a] hearing will not be granted on issues of policy or law." 21 C.F.R. §12.24(b)(1).

It is important to stress that the sole administrative right provided to Mr. Copanos under FDA's regulations was an opportunity to request a hearing, not an opportunity to raise legal or policy objections. This, in turn, could be granted only if Mr. Copanos identified specific facts in dispute that justified a hearing. FDA never informed Mr. Copanos that he also might raise independent *legal* arguments opposing his debarment, and FDA's procedural regulations, in fact, seem to preclude that possibility. Indeed, the only procedural regulation that authorizes parties to submit and FDA to rule upon "objections,"as opposed to requests for a hearing, is framed to apply exclusively to certain proposed regulations; it has no applicability whatsoever to proposed orders, such as debarment orders.[3] Id. §12.30.

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[3] It is unclear precisely which procedural regulations apply to debarment orders.

Furthermore, even if Mr. Copanos, as a practical matter, "could have" raised his legal arguments with FDA as the court of appeals ruled, and even if other, more prudent individuals did raise such arguments in their debarment proceedings, the force of this argument is not blunted. Because of the substantial due process and fundamental fairness concerns raised whenever a court restricts a party's access to judicial review, this Court has indicated that the first criterion of the McCarthy balancing test is satisfied whenever there is "*some doubt* as to whether the agency was empowered to grant effective relief." 503 U.S. at 146 (internal quotations marks and citations omitted) (emphasis added). In light of the inconsistent and uncertain scope of FDA's notice and procedural regulations, there can be little controversy that this "some doubt" threshold has been crossed in this case.

Moreover, it simply does not comport with the fundamental notions of fairness embodied by the Due Process clause of the Fifth Amendment to penalize Mr. Copanos through application of the waiver doctrine for failing to raise his legal arguments before the agency. See Mullane v. Central Hanover Bank & Trust Co., 339 U.S. 306, 314 (1950) (elementary requirement of due process is "notice reasonably

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According to both FDA's notice to Mr. Copanos and regulations set forth at 21 C.F.R. §10.50(c)(20), debarment proceedings are governed by the procedures specified at Part 12 of FDA's regulations. By their express terms, however, many critical provisions of Part 12, including the procedures for initiating a hearing and filing requests for hearing, do not appear applicable to debarment proceedings and instead apply primarily to drug approval and withdrawal decisions. See, e.g., 21 C.F.R. §12.21. In fact, FDA has never promulgated, or even proposed, specific regulations applicable to debarment proceedings. Instead, it has sought to squeeze them into a context designed for distinctly different categories of regulatory activities. Debarment is a square peg ill-fitting a round hole. This situation further underscores the stunning lack of clarity associated with FDA's debarment proceedings.

calculated, under all the circumstances to apprise interested parties of the pendency of the action and afford them an opportunity to present their objections"); see also Hess & Clark, Div. of Rhodia, Inc. v. FDA, 495 F.2d 975 (D.C. Cir. 1975) (vacating FDA summary judgment order because of inadequate notice).

Even if this Court were to construe FDA's notice and regulations as loosely as possible, they are, at best, highly ambiguous and fail to clearly indicate whether or not FDA will entertain legal or policy arguments. While a petitioner faced with such uncertainty would be well-advised to raise all available arguments before FDA, any ambiguity in FDA's notice, as a matter of law, must be construed against FDA, not Mr. Copanos. As the court of appeals consistently has stated: "[W]hen the sanction is as drastic as dismissal without any consideration whatever of the merits, *elementary fairness compels clarity in the notice of the material required as a condition for consideration.*" Radio Athens, Inc., (WATH) v. F.C.C., 401 F.2d 398, 404 (D.C. Cir. 1968) (emphasis added); accord Salzer v. F.C.C., 778 F.2d 869, 875 (D.C. Cir. 1985).

Because FDA's notice and regulations created "some doubt" as to whether FDA would consider purely legal objections in its debarment proceedings, the first criterion of the McCarthy balancing test weighs heavily in favor of permitting judicial review of Mr. Copanos' legal arguments.

2. FDA Already Has "Predetermined" The Legal Issue Whether, As A Matter Of Statutory Construction, The Debarment Statute Can Be Applied Retroactively

Mr. Copanos' strong interest in obtaining prompt judicial review is further bolstered by the fact that, at the time of his submission, FDA already had "predetermined" the retroactivity issue raised in this case, thereby making further recourse to the agency futile. See McCarthy, 503 U.S. at 147-49. As the court of appeals previously has explained, the exhaustion requirement may be excused for a particular issue "when the agency has in fact considered the issue." Natural Resources Defense Council, Inc. v. U.S.E.P.A., 824 F.2d 1146, 1151 (D.C. Cir. 1987) (citing Etelson v. Office of Personnel Management, 684 F.2d 918, 923 (D.C. Cir. 1982)).

Prior to this case, FDA addressed in at least four published decisions the precise retroactivity issue raised below by Petitioner.[4] That issue is whether, as a matter of statutory construction, mandatory debarment under 21 U.S.C. §335a(a)(2) can be applied retroactively to an individual whose conviction predated passage of the GDEA. In each of its previous debarment decisions, FDA relied upon virtually identical reasoning to reach the same conclusion; that Congress intended the mandatory debarment provision of the GDEA to operate retroactively. See, e.g., 59 Fed. Reg. 55670. Thus, the primary purpose of the exhaustion requirement had previously been substantially served because FDA was afforded an

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[4] See 59 Fed. Reg. 55670 (Nov. 8, 1994) (Ashok Patel); 59 Fed. Reg. 751 (Jan. 6, 1994) (David Brancato); 58 Fed. Reg. 59046 (Nov. 5, 1993) (Liaquat Hossain); 58 Fed. Reg. 54156 (Oct. 20, 1993) (Raj Matkari).

opportunity to consider and to rule upon the retroactivity issue prior to judicial review being taken by Petitioner.

Petitioner respectfully suggests that, contrary to the court of appeals' ruling, it is irrelevant whether FDA has considered and disposed of the retroactivity issue in the pending proceeding involving Mr. Copanos or in prior proceedings involving other individuals, as long as its disposition indicates that further recourse to the agency would be futile. See Etelson, 684 F.2d at 925 (exhaustion unnecessary when, *inter alia*, agency "has made known that its general views are contrary to those of the complainant"); accord Hatcher v. Department of the Air Force, 705 F.2d 1309, 1312 n.2 (11th Cir. 1983), reh'g denied, 712 F.2d 1419 (11th Cir. 1983) (holding that exhaustion was futile in light of prior agency decision in another case).

Prior to this case, the agency had addressed the statutory retroactivity argument on at least four prior occasions, had published those decisions in the Federal Register, and had never demonstrated any willingness to reconsider its announced position. Consequently, FDA has predetermined the issue within the meaning of the McCarthy test, and further recourse to the agency is unnecessary. The retroactivity issue is now a proper subject for judicial resolution by the court of appeals in this case.

3. The Institutional Interests In Requiring Exhaustion Are Particularly Attenuated In This Case

Finally, in contrast to Mr. Copanos' compelling interest in obtaining prompt judicial review of his legal objections to FDA's *ultra vires* debarment order, the institutional interests

(both FDA's and the court's) in requiring exhaustion in this case are particularly attenuated. The issues being raised by Mr. Copanos are purely legal and do not implicate either FDA's "discretionary power" or its "special expertise." See McCarthy, 503 U.S. at 145. Nor is there any indication that the agency's administrative processes are being deliberately flouted in the instant case. See id. Although Mr. Copanos' request for a hearing before the FDA may have failed to raise all available legal and policy arguments, it fully comports with a reasonable interpretation of FDA's notice and procedural regulations, which indicated that legal and policy arguments would not be considered by FDA. Moreover, further administrative proceedings would not produce a useful record for subsequent judicial consideration in this case, as all relevant facts currently are part of the administrative record (or are in the public domain and may be judicially noted), and are not in dispute in any event. See id.

In sum, virtually none of the purposes underlying the exhaustion doctrine is served by the court of appeals' refusal to entertain Mr. Copanos' substantive, legal claims. By not addressing these underlying factors, the panel simultaneously has failed to take into account valid and binding Supreme Court and D.C. Circuit precedent on the exhaustion issue and, as discussed above, has raised serious constitutional issues adversely affecting Mr. Copanos' Fifth Amendment due process rights. Because the issues raised in this petition for certiorari touch upon the integrity of the judicial process itself, this is a matter of exceptional importance not only to Mr. Copanos, but also to this court and to the rule of law and thus calls for an exercise of this court's supervisory powers.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 96-1128 **September Term, 1996**

John D. Copanos,
Petitioner

v.

Food and Drug Administration and
United States of America,
Respondents

[Stamp]
United States Court of Appeals
For the District of Columbia Circuit
FILED Jan 29 1997

Petition for Review of a Final
Order of the Food and Drug Administration

Before: SILBERMAN and SENTELLE, *Circuit Judges*, and BUCKLEY, *Senior Circuit Judge*

JUDGMENT

This cause was considered on a petition for review of an order of the Food and Drug Administration, and was briefed by counsel. While some of the issues presented occasion no need for a published opinion, they have been accorded full consideration by the court. *See* D.C. Cir. R. 36(b) (January 1, 1994). On consideration thereof, it is

ORDERED and **ADJUDGED,** by this Court, that the petition for review is hereby denied. Petitioner waived his retroactivity and constitutional arguments by failing to raise them before the FDA. *DiCola v. FDA*, 77 F.3d 504, 506 n.* (D.C. Cir. 1996). Petitioner clearly did not raise these

arguments in his request for a hearing; indeed, his reference to the "retro-active [sic] legislation," could be interpreted as an admission that 21 U.S.C. §355a(a)(1994) applies retroactively. Although FDA regulations and the notice of debarment indicate that hearings are granted only where genuine issues of fact exist, petitioner — like the petitioner in *DiCola* — could have raised these legal arguments in his request for a hearing or in a petition for reconsideration, and the FDA has addressed legal argument made in other requests for hearing. *See, e.g.*, 59 Fed. Reg. 55,670, 55,671-72 (Nov. 8, 1994). And whether other parties have raised the retroactivity argument in other proceedings is irrelevant, as no one raised this argument in this proceeding. Nor is there a compelling reason not to apply the waiver doctrine, this is not a case "where a matter of great importance is at stake. [Petitioner's] waiver is not likely ... to have an adverse impact upon anyone but himself." *DiCola*, 77 F.3d at 506 n.* (internal quotations and citations omitted). It is

FURTHER ORDERED, by this Court, *sua sponte*, that the Clerk shall withhold issuance of a mandate herein until seven days after disposition of any timely petition for rehearing. *See* D.C. Cir. R. 41(a)(1) (January 1, 1994). This instruction to the Clerk is without prejudice to the right of any party at any time to move for expedited issuance of the mandate for good cause shown.

Per Curiam
FOR THE COURT:

Mark J. Langer, Clerk

John D. Copanos; Denial of Hearing; Final Debarment Order
[Federal Register: March 11, 1996 (Volume 61, Number 48)]
[Notices]
[Page 9711-9713]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. 94N-0033]

John D. Copanos; Denial of Hearing; Final Debarment Order

Food and Drug Administration, HHS.

Notice.

The Food and Drug Administration (FDA) denies John D. Copanos'
request for a hearing and issues a final order under section 306(a) of
the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 335a(a)) permanently debarring John D. Copanos, 6504 Montrose Ave., Baltimore, MD 21212, from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on its finding that Mr. Copanos was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act.

EFFECTIVE DATE: March 11, 1996

Application for termination of debarment to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., Rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-2041.

SUPPLEMENTARY INFORMATION:

I. Background-

John D. Copanos was the owner and president of John D. Copanos and Sons, Inc., and Kanasco, Ltd., when, on November 13, 1989, he agreed to plead guilty to one count of distributing misbranded drugs with intent to mislead, a Federal felony offense under sections 301(a) of the act (21 U.S.C. 331(a)) and 303(a)(2)(previously 303(b)) of the act (21 U.S.C. 333(a)(2)) (previously 21 U.S.C. 333(b)), and one count of causing the adulteration of drugs with intent to mislead, a Federal felony offense under sections 301(k) and 303(a)(2) of the act. On February 16, 1990, the United States District Court for the District of Maryland accepted Mr. Copanos' plea of guilty and entered judgment against him for these felonies. The bases for these convictions were as follows.

Mr. Copanos distributed a drug that was misbranded because its labeling failed to bear adequate directions for use and because it failed to warn of the presence of phenylalanine, a component of aspartame. In fact, adequate testing had not been conducted to determine the effect of aspartame on the stability, potency, and effectiveness of this drug. This drug was also

misbranded because it failed to reveal the presence and amount of phenylalanine.

In addition, Mr. Copanos pled guilty to causing the adulteration of a drug with intent to mislead by failing to comply with current good manufacturing practice.

In a notice published in the Federal Register of November 9, 1994 (59 FR 55846), FDA offered Mr. Copanos an opportunity for a hearing on the agency's proposal to issue an order under section 306(a) of the act debarring Mr. Copanos from providing services in any capacity to a person that has an approved or pending drug product application. FDA based the proposal to debar Mr. Copanos on its finding that he had been convicted of felonies under Federal law for conduct relating to the regulation of a drug product. -

In the Federal Register notice of November 9, 1994, FDA informed Mr. Copanos that his request for a hearing could not rest upon mere allegations or denials but must present specific facts showing that there was a genuine and substantial issue of fact requiring a hearing. FDA also informed Mr. Copanos that if it conclusively appeared from the face of the information and factual analyses in his request for a hearing that there was no genuine and substantial issue of fact which precluded the order of debarment, FDA would enter summaryjudgment against him and deny his request for a hearing.

In a letter dated December 8, 1994, Mr. Copanos requested a hearing, and in a letter dated January 6, 1995, Mr. Copanos submitted arguments and information in support of his hearing request. In his request for a hearing, Mr. Copanos does not dispute that he was convicted of a felony under Federal law as alleged by FDA. However, Mr. Copanos argues that: (1) He did not receive proper notice; (2) he is entitled to a hearing to contest or explain the facts underlying his plea; (3) some factual

statements in the agency's proposal are inaccurate; (4) the agency's reliance on portions of the indictment is inappropriate; (5) and the agency's proposal to debar him is unconstitutional.

The Deputy Commissioner for Operations has considered Mr. Copanos' arguments and concludes that they are unpersuasive and fail to raise a genuine and substantial issue of fact requiring a hearing. Moreover, the legal arguments that Mr. Copanos offers do not create the bases for a hearing (see 21 CFR 12.24(b)(1)). Mr. Copanos' arguments are discussed below.

II. Mr. Copanos' Arguments in Support of a Hearing

A. Notice

Mr. Copanos objects to being notified of his proposed debarment through publication in the Federal Register. It is the policy of the agency to send a notice of proposed debarment by certified mail. If certified mail delivery is unsuccessful, the agency attempts to deliver the notice to the individual personally. If this attempt fails also, [[Page 9712]] notice is given through publication in the Federal Register. FDA attempted to serve Mr. Copanos by certified mail but was unable to do so. In September 1994, FDA's Baltimore District Office learned that Mr. Copanos was out of the country. Agents from FDA's Baltimore District Office visited Mr. Copanos' home weekly to determine if he had returned. FDA's Office of Criminal Investigation arranged with U.S. Customs to be notified if Mr. Copanos returned to the country. When Mr. Copanos did not return to the country, the debarment notice was published in the Federal Register on November 9, 1994.

Mr. Copanos requested a hearing on his proposed debarment and made arguments in support of that request. Thus, it is clear that Mr. Copanos received actual notice of the agency's

proposed action and has not been deprived of any procedural rights by virtue of publication of the debarment notice in the Federal Register.

B. Facts Underlying the Plea

Mr. Copanos makes the following statements relating to the facts underlying his plea. He states that he held a management position and did not personally misbrand or manufacture adulterated drugs, that none of the drugs or products involved were put into commerce, and that the first count of the plea related to a facility that was not under his full control at the time. Mr. Copanos also states that the agency's proposal sets forth areas of indictment information and factual statements of allegations rather than actual proof.

Mr. Copanos is correct that the agency's proposal contained some inaccuracies. Although Mr. Copanos pled guilty to counts four and six of the indictment against him, he did not plead guilty to all the particulars listed in the indictment. In its debarment proposal, the agency mistakenly referred to parts of the indictment to which Mr. Copanos did not plead. The agency very much regrets this error. However, this misplaced reliance does not raise a genuine and substantial issue of fact requiring a hearing.

The act requires FDA to mandatorily debar an individual who has been convicted of certain Federal felonies. The only relevant factual issue is whether Mr. Copanos was, in fact, convicted. Mr. Copanos does not dispute that he pled guilty to two Federal felony counts for actions that relate to the regulation of a drug product. Section 306(l) of the act includes in its definition of a conviction, a guilty plea. Accordingly, Mr. Copanos' statements regarding the factual circumstances underlying his plea fail to raise a genuine and substantial issue of fact justifying a hearing.

C. Ex Post Facto Argument

Mr. Copanos argues that the ex post facto clause of the U.S. Constitution prohibits application of section 306(a)(2) of the act to him because this section was not in effect at the time of Mr. Copanos' criminal conduct. The Generic Drug Enforcement Act (GDEA) of 1992, including section 306(a)(2), was enacted on May 13, 1992, and Mr. Copanos was convicted on February 16, 1990.

An ex post facto law is one that reaches back to punish acts that occurred before enactment of the law or that adds a new punishment to one that was in effect when the crime was committed. (Ex Parte Garland, 4 Wall. 333, 377, 18 L. Ed. 366 (1866); Collins v. Youngblood, 497 U.S. 37 (1990).)

Mr. Copanos' claim that application of the mandatory debarment provisions of the act is prohibited by the ex post facto clause is unpersuasive, because the intent of debarment is remedial, not punitive. Congress created the GDEA in response to findings of fraud and corruption in the generic drug industry. Both the language of the GDEA and its legislative history reveal that the purpose of the debarment provisions set forth in the GDEA is ``to restore and ensure the integrity of the abbreviated new drug application (ANDA) approval process and to protect the public health." (See section 1, Pub. L. 102-282, GDEA of 1992.)

In a suit challenging a debarment order issued by FDA (58 FR 69368, December 30, 1993), the constitutionality of the debarment provision was upheld against a similar challenge under the ex post facto clause. The reviewing court affirmed the remedial character of debarment:

Without question, the GDEA serves compelling governmental interests unrelated to punishment. The punitive

effects of the GDEA are merely incidental to its overriding purpose to safeguard the integrity of the generic drug industry while protecting public health. Bae v. Shalala, 44 F.3d 489, 493 (7th Cir. 1995). Because the intent of the GDEA is remedial rather than punitive, Mr. Copanos' argument that the GDEA violates the ex post facto clause must fail. See id. at 496-97.

D. Miscellaneous Arguments

Mr. Copanos argues that his debarment would be ``an unconstitutional taking of the right to earn a living in the United States." It appears that Mr. Copanos is referring to a ``taking" of property under the Fifth Amendment. Mr. Copanos further states that he has sold his company, including all of its approved applications, and that to debar him now ``would be a malicious act" on the part of the agency. Mr. Copanos also argues that he should not be debarred because his guilty plea was made at an emotional and stressful time.

None of these arguments raise a genuine and substantial issue of fact requiring resolution at a hearing. Mr. Copanos has not established that his debarment affects any property interest protected by the Fifth Amendment. The expectation of employment is not recognized as a protected property interest under the Fifth Amendment. Hoopa Valley Tribe v. Christie, 812 F.2d 1097, 1102 (9th Cir. 1986); Chang v. United States, 859 F.2d 893, 896-97 (Fed. Cir. 1988). Loss of potential profit is not a sufficient basis for a ``takings" claim. Andrus v. Allard, 444 U.S. 51, 66 (1979). To have a protected property interest, one must have a ``legitimate claim of entitlement" to that interest. Erikson v. United States, 67 F.3d 858 (9th Cir. 1995). One who voluntarily enters a pervasively regulated industry, such as the pharmaceutical industry, and then violates its regulations, cannot successfully claim that he has a protected property interest when he is no longer entitled to the benefits of that industry. Id.

Mr. Copanos does not dispute that he was convicted as alleged by FDA. Under section 306(l)(1)(B) of the act a conviction includes a guilty plea. The facts underlying Mr. Copanos' conviction are not at issue. Moreover, the act does not permit consideration of factors such as emotional stress; rather, the act is clear that an individual shall be debarred if convicted of a felony under Federal law for conduct relating to the regulation of any drug product (see section 306(a)(2)(B) of the act). Mr. Copanos has been convicted of such a felony. Accordingly, the Deputy Commissioner for Operations denies Mr. Copanos' request for a hearing.

III. Findings and Order

Therefore, the Deputy Commissioner for Operations, under section 306(a) of the act and under authority delegated to him (21 CFR 5.20), finds that John D. Copanos has been convicted of felonies under Federal law for conduct relating to the regulation of a drug product (21 U.S.C. 335a(a)(2)(B)).

As a result of the foregoing findings, John D. Copanos is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application [[Page 9713]]under section 505, 507, 512, or 802 of the act (21 U.S.C. 355, 357, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (insert date of publication in the Federal Register), (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii)). Any person with an approved or pending drug product application who knowingly uses the services of Mr. Copanos, in any capacity, during his period of debarment, will be subject to a civil money penalty (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Mr. Copanos, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to a civil penalty (section 307(a)(7) of the act). In addition, FDA will not accept or review

any ANDA or abbreviated antibiotic drug application submitted by or with Mr. Copanos' assistance during his period of debarment.

Mr. Copanos may file an application to attempt to terminate his debarment pursuant to section 306(d)(4)(A) of the act. Any such application would be reviewed under the criteria and processes set forth in section 306(d)(4)(C) and (d)(4)(D) of the act. Such an application should be identified with Docket No. 94N-0033 and sent to the Dockets Management Branch (address above). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 22, 1996.
Michael A. Friedman,
Deputy Commissioner for Operations.
[FR Doc. 96-5687 Filed 3-8-96; 8:45 am]

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 96-1128 **September Term, 1996**

John D. Copanos,
Petitioner

v.

[Stamp]
United States Court of Appeals
For the District of Columbia
Circuit
FILED Mar 28 1997

Food and Drug Administration and
United States of America,
Respondents

BEFORE: Silberman and Sentelle, Circuit Judges,
And Buckley, Senior Court Judge

ORDER

Upon consideration of petitioner's petition for rehearing filed March 10, 1997, it is

ORDERED that the petition be denied.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk

BY:

Robert A. Bonner
Deputy Clerk